SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5161-5200

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality and purity fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; Section 501 (d), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (l), the article purported to be and was represented as a drug composed wholly or partly of penicillin or a derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507.

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

5161. Extar (liquid dentifrice). (F. D. C. No. 39412. S. No. 46-689 M.)

QUANTITY: 72 ctns., 6 btls. each, at Trenton, N. J.

SHIPPED: 6-14-56, from Philadelphia, Pa., by Extar Division, A. J. Parker Co.

LABEL IN PART: (Ctn.) "Extar"; (btl.) "Contents: 67 Gm. * * * Liquid Dentifrice."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 12 percent ethylenediaminetetra acetic acid, together with inorganic sodium phosphates.

LIBELED: 8-7-56, Dist. N. J.

CHARGE: 505 (a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

Disposition: 9-7-56. Default—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR VETERINARY USE

5162. Anchor Anti-Blote. (F. D. C. No. 39153. S. No. 25-958 M.)

QUANTITY: 40 2-lb. cans at Des Moines, Iowa.

SHIPPED: 6-1-56, from St. Joseph, Mo., by Anchor Serum Co.

LABEL IN PART: (Can) "500 Doses Anchor Anti-Blote A Bloat Preventive for Cattle Veterinary Use Only * * * Each 2 Pounds Contain: Active Ingredients: Procaine Penicillin G, 37,500,000 Units."

LIBELED: 7-6-56, S. Dist. Iowa.

CHARGE: 502 (1)—when shipped, the article contained penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to law; and the article had not been exempted from requirements of certification by regulations.

DISPOSITION: 9-7-56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

5163. Dainty-Maid Service drug and device and Dainty-Maid Personal Powder (2 seizure actions). (F. D. C. No. 33575. S. Nos. 54-165 L, 54-167 L.)

QUANTITY: 84 pkgs. of Dainty-Maid Service and 35 ctns. of Dainty-Maid Personal Powder at Detroit, Mich.

SHIPPED: 6-4-52 and 7-7-52, from Middlefield, Conn., by Dainty Maid, Inc.

LABEL IN PART: (Pkg.) "Dainty-maid Service"; (ctn.) "Dainty-maid Personal Powder * * * Contains: Boric Acid, Zinc Sulfate, Salicylic Acid, Sodium Chloride and Tannic Acid."

Accompanying Labeling: Booklets entitled "Why must this crucial subject be Hush-Hush?" and "Profitable Suggestions For The New Dealer"; leaflets entitled "Here is an opportunity you can't afford to miss," "A Dignified Fascinating New Profession," and "Modern Heat Therapy"; charts entitled "Eight Reasons for Owning a Dainty-Maid Service"; and book entitled "Mary Coleman's Training Course In Personal Hygiene."

RESULTS OF INVESTIGATION: Each Dainty-Maid Service package contained 1 rubber douche bag, 1 porcelain vaginal syringe, 1 carton of Dainty-Maid Personal Powder, 2 pieces of rubber tubing, 1 rubber rectal tube, 1 glass "Earigator," 1 metal clamp, 1 plastic measuring scoop, and 1 leaflet entitled "Instructions."

Libeled: 9-9-52, E. Dist. Mich.; amended 1-27-56.

CHARGE: 502 (a)—when shipped, the labeling of the articles contained false and misleading representations that the articles provided an adequate and effective treatment for preventing women from fading early in life and becoming nagging, irritable, cruel, emaciated, and scrawny; for preventing rough and pimpled skins, wrinkles on young faces, headaches, tiredness, enervation, and constant fatigue; for providing a buoyant, vibrant life; for increased vaginal discharge, leucorrhea, Trichomonas vaginalis, nonspecific vaginitis, and pelvic inflammatory conditions; for providing increased circulation of the blood throughout the entire body; for diseased organs, painful menstruation, and inflammation of the bladder; for stimulating the circulation, so that the glands function naturally; for minimizing "hot flashes" in older women, combatting all kinds and conditions of feminine disorders, and clearing up and preventing the occurrence of many of the most distressing of women's diseases and deplorable aftereffects; for menopausal symptoms. such as "hot flashes," nervous irritability, peevishness, and depressions; for senile vaginitis, painful menstruation, and profuse menstruation; for preventing and destroying ovarian cysts; and for falling of the womb, anteversion